



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,172	07/25/2001	Oren Globerman	110/02239	7714

44909 7590 03/20/2006

WOLF, BLOCK, SCHORR & SOLIS-COHEN LLP
250 PARK AVENUE
NEW YORK, NY 10177

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,172

Applicant(s)

GLOBERMAN ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32,34-106,110-112,116-124,148,209,211,212,214-221 and 224-231 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 214-216,220,221 and 224-229 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 5,25,26,29,32,45,47,49,50,65,67,72-74,79,82,83,96,97,120,217 and 218 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims rejected are 1-4,6-24,27,28,30,31,34-44,46,48,51-64,66,68-71,75-78,80,81,84-95,98-106,110-112,116-119,121-124,148,209,211,212,219,222,223,230 and 231.

Claim Objections

Claims 2, 3, 65, 67, 148, 217, and 218 are objected to because of the following informalities:

With regard to claims 2, 3, and 148, the terminology “axially displaced extensions” lacks clear antecedent basis from base claim 1 (emphasis added). Rather, it appears that only “axially displaced slits” has clear antecedent basis. The Examiner suggests changing “extensions” with “slits” in order to overcome this objection.

With regard to claim 148, it is not clear where the claimed structure has support from the remainder and where it is shown in the drawings. Appropriate correction is required.

Regarding claims 65, 67, 217, and 218, the terminology “tube axis” is not clear because it is not clear which tube axis is being referenced . There are at least two tube axes inherent to tubes: the longitudinal axes and the radial axes. The Examiner suggest inserting the term “longitudinal” before “axis” in these claims in order to overcome this objection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-16, 19-24, 27, 28, 30, 31, 34, 35, 41-44, 46, 48, 51-62, 64, 66, 68, 70, 78, 80, 81, 84, 86, 90-95, 98-103, 106, 110, 111, 121-124, 148, 209, 211, 230, and

231 are rejected under 35 U.S.C. 102(b) as being anticipated by Pisharodi (US 5,693,100). Pisharodi anticipates the claim language where the tube as claimed is shown in Figure 7 of Pisharodi (see also column 7, lines 27-37), the slits as claimed are between sections (34), the axial displaced extensions are the combination or pair of axial aligned legs (34,36), and the locking element is the screw (42) with locknut (40); see the figures, column 4, line 58 to column 5, line 46. Since the extensions of Pisharodi extend generally in a direction normal to the tube axis, the claim language is considered fully met. It is noted that the axial displaced slits need not be along the longitudinal axis of the tube but can be along any axis even an axis transverse to the longitudinal axis.

By looking at Figures 5 and 6 for reference, it is clear that each leg (34) produces a peak, there are two peaks shown along each pair of legs and there is a portion radially inward of the peaks in this axially compressed configuration. This same structure would also be present in the embodiment of Figure 7 where the axially compressed configuration is not shown. For this reason, the Examiner asserts that the claim language is fully met.

Regarding claim 9, the slits between the legs are perpendicular or not parallel to the longitudinal axis.

Regarding claim 11, slits along the axis are of a different length than the slit between the legs.

Regarding claim 30, Pisharodi has two segments along the longitudinal axis.

Regarding claims 56, 59, and 64, the cross-section claimed can be taken at an angle across any part of the device such that the claim language is fully met to the extent it can be given patentable weight.

Regarding claim 81, see Figure 6 or 7 where the bottom subunits (36) are connected at their tops.

Regarding claim 98-102, the claim language does not require that the deformation will only take place at the values set forth herein, and thus, the claim language is read on by what is disclosed by Pisharodi.

Regarding claim 209, the transaxial direction is the radial direction and all 16 extend in the same transaxial or radial direction.

It appears that claims 75-77 are read on by Pisharodi also, but they are not included in the rejection in that doing so would require the action be made non-final, thus, slowing prosecution.

Claims 1, 69-71, 75-78, 80, 87, 88, and 98-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (US 5,059,193) where the slits are displaced along the circumferential axis and the interconnecting element is the netting (200); see the figures and the front page. The unexpanded portions are at the ends of the Kuslich device where the expanding ribs (26) are joined to the rest of the body (12).

With regard to claim 69-71, the tabs as claimed are the ratchet teeth of Kuslich.

With regard to claim 87, Applicant is directed to Figure 3 of Kuslich.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-40, 63, 104, 105, and 212 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) alone.

Regarding claims 36-40, Pisharodi discloses a rectangular and truncated triangle cross-sectional profile in the two embodiments disclosed; see the Figures. But Pisharodi fails to disclose the use of the cross-sectional profiles claimed. However, since Pisharodi discloses different profiles, it is the Examiner's position that it would have been considered prima facie obvious to use other profiles including those claimed because it is not clear that the different profiles would result in a substantially different operation or function from that of Pisharodi.

Pisharodi meets the claim language except for the elliptical cross-sectioned tube (claim 63). However, since Pisharodi discloses at least two cross-sectional shapes (i.e. rectangular and octagonal), it is the Examiner's position that it would have been considered prima facie obvious to use other profiles in Pisharodi in order to accommodate other numbers of leg projections.

Regarding claims 104-105, since the diameter of expansion can be incrementally varied, it follows that small fractions over the unexpanded diameter are possible with

Art Unit: 3738

Pisharodi's device such that the claimed diameter is clearly obvious over Pisharodi alone.

With regard to claim 212, Pisharodi fails to disclose the relative diameters of the expanded and non-expanded diameters as claimed. However, the mere designation of the size or proportion is not considered patentable because Pisharodi appears to disclose something at least near the claimed range and it would have been obvious to make the Pisharodi's device expand more or less depending upon the size and needs of the particular patient. It is noted that Pisharodi's device is adjustable indicating that it would have been obvious to adjust it to the size of the patient.

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 85 and 89 are rejected under 35 U.S.C. 102(b) as anticipated by Pisharodi (US 5,693,100) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pisharodi (US 5,693,100) alone. Pisharodi fails to disclose the process of making step claimed of annealing the device. However, the Examiner asserts that such a process step would not result in a different product from that of Pisharodi; see MPEP 2113, which is incorporated herein by reference thereto.

Alternatively, if annealing does result in a different product, it appears to only result in a slightly different product such that the claimed invention would have been considered at least clearly obvious to an ordinary artisan.

Claims 17, 18, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) in view of Pisharodi (US 5,123,926).

Regarding claims 17, 18, and 119, Pisharodi discloses an expandable spacer but lacks the teaching of spurs on the spacer as claim. Pisharodi teaches of an artificial spine prosthesis with spurs (Fig. 3, Ref. Num. 8) to hold the prosthesis within the intervertebral disk space. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Pisharodi to have spurs on the outside of the spacer to better hold it in place.

Claims 116-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) in view of Stubstad et al (US 3,867,728). Pisharodi meets the claim language as explained above, but fails to teach a coating of bioactive material as claimed. However, Stubstad teaches that it was known to use bioactive coatings to improve or prevent ingrowth; see column 11, lines 39-65. Therefore, it is the Examiner's position that it would have been obvious to put a bioactive coating on Pisharodi's device for the same reasons that Stubstad does the same.

Response to Arguments

Applicant's arguments with respect to have been considered but were considered moot in view of the new interpretation of the applied references. In the Examiner's view and contrary to the Applicants' statement, the expanding portions Pisharodi and Kuslich are attached to unexpanding portions of their respective devices. For this reason, the rejections have been maintained with a different interpretation for Pisharodi.

Allowable Subject Matter

Claims 5, 25, 26, 29, 32, 45, 47, 49, 50, 65, 67, 72-74, 79, 82, 83, 96, 97, 217, 218, and 120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 120, the Examiner is interpreting the claim language as comparing one extension to another extension of the claimed axial tube.

Regarding claims 65, 67, 217, and 218, the Examiner is interpreting "tube axis" as being the longitudinal axis of the tube.

Claims 214-216, 220, 221, and 224-229 are allowable over the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure

Art Unit: 3738

outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738